REMARKS

In the Action mailed January 18, 2005, the Examiner rejected claims 1-4, 7-18, 23, 24, 35, and 36, and withdrew from consideration claims 5, 6, 19-22, 25-34 and 37. The Examiner also objected to dependent claims 38 and 39, but indicated that these claims would be allowable if rewritten in independent form. In response, Applicant has amended claims 1 and 10, has canceled claims 25-34, and has added claims 40-43. As such, claims 1-24 and 35-43 remain pending (although, of these, claims 5, 6, 19-22 and 37 are claims that were previously withdrawn from consideration).

In view of the amendments to the claims and the following remarks, Applicant requests reconsideration of the patentability of currently pending claims 1-4, 7-18, 23, 24, 35, 36, 38 and 39; asks that the Examiner consider, pursuant to 37 CFR 1.141, the patentability of previously withdrawn claims 5, 6, 19-22 and 37 as being in dependent form and including all the limitations of an allowed generic claim; and asks that the Examiner consider newly added claims 40-43.

Applicant also asks that the Examiner consider the references cited in the supplemental information disclosure statement filed January 11, 2005, before the January 18, 2005 mailing of the Action to which this Amendment is directed.

Election / Restrictions

The Examiner required that Applicant elect a single one of five disclosed species for prosecution on the merits to which the claims would be restricted if no generic claim is finally held to be allowable. Applicant affirms that on December 20, 2004, a provisional election was made with traverse to prosecute the invention of species 1, claims 1-4, 7-18, 23-24, 35-36, 38, and 39. However, the telephone conversation on December 20, 2004 was with the undersigned, Stephen R. Schaefer, and not the inventor Kent Harrison, as the Examiner's Action indicates.

Upon review of this Action, Applicant wishes to make its election without traverse, rather than with traverse, as originally indicated to the Examiner. As discussed later in these remarks, Applicant contends that certain pending generic claims are allowable, and that the claims to

additional species that are written in dependent form and include all of the limitations of the generic claims are entitled to consideration and allowance.

Claim Rejections – 35 U.S.C. §§ 102 and 103

The examiner rejected claims 1-4 and 7-17 under 35 U.S.C. 102(b) as being anticipated by Boyd et al. (U.S. Patent 5,799,661). Of these, claims 1 and 10 are independent claims. Although the Examiner also stated that claims 35 and 36 were also being rejected under 102(b) as being anticipated, Applicant believes that statement to be a mistake in view of the Examiner's statement later in the Action that not all limitations of claims 35 and 36 are met by the Boyd et al. reference. The Examiner also rejected dependent claims 18, 23 and 24 (which depend from independent claim 10) under 35 U.S.C. 103(a) as being obvious in view of Boyd et al., either alone or in combination with other references.

The Examiner rejected independent claim 35 and dependent claim 36 under 35 U.S.C. 103(a) as being obvious in view of a combination of Boyd et al. and U.S. Patent 5,837,003 to Ginsberg. In this regard, the Examiner conceded that Boyd et al. do not specifically disclose a method of use within a blood vessel, as is required by claims 35 and 36, but contended that Ginsberg teaches a catheter for cooling a body and a method for positioning the catheter within a blood vessel and deploying a balloon to cool tissue. The Examiner further contended it would have been obvious to one having ordinary skill in the art at the time of the invention was made to use the deployable patch as taught by Boyd et al. within a blood vessel as taught by Ginsberg, because, according to the Examiner, the patch is designed for delivery via a small diameter cannula and would provide increased surface area for cooling.

Applicant has amended independent claims 1 and 10 so that each now recites that the elongate body distal end be for entry into a body vessel. These amendments adds no new matter. Applicant submits that independent claims 1 and 10, as amended, and claim 35 are each directed to subject matter that is patentable over Boyd et al., either alone or in combination with any other reference.

Independent claim 1, as amended, is directed to a medical device with an elongate body having a distal end for entry into a body vessel and positionable near a target tissue region of the

body. The medical device of claim 1 also has a structure deployable from the distal end of the elongate body to cool the target tissue region. Independent claim 10, as amended, is similar to claim 1 but specifically requires that the deployable structure of the medical device be a patch. Independent claim 35 is directed to a method of cooling a target tissue region inside a body, and requires, among other things, the introduction of a distal portion of a catheter into a body vessel.

Boyd et al. discloses devices and methods for performing port-access or closed-chest coronary artery bypass surgery, including a topical hypothermia device for use during a port-access bypass procedure. The topical hypothermia device has a flexible heat exchanger that is collapsible into a pre-deployable position to fit through an access port into the chest of a patient. The topical hypothermia device also includes a tubular shaft made of a rigid material, such as stainless steel or a rigid plastic. Once inserted into a patient through a chest access port, the flexible heat exchanger is deployed from the topical hypothermia device and placed under the heart for cooling.

Ginsburg discloses a balloon catheter that may be placed into a patient's blood vessel for heating or cooling of blood flowing through the vessel. To heat or cool the blood, fluid is supplied to the balloon through an inflow lumen, which causes the balloon to inflate around the catheter and create a heat transfer region. The balloon is inflated to a diameter somewhat less than internal diameter of the blood vessel so as not to unduly impede the flow of blood through the vessel.

Device Claims 1 and 10 and their Dependents

Boyd et al. do not anticipate either of independent claims 1 or 10, as amended. For example, the topical hypothermia device disclosed in Boyd et al. does not have a distal end for entry into a body vessel as recited in claims 1 and 10. Rather, the topical hypothermia device in Boyd et al. enters the body through a chest port and has a rigid tubular shaft that is not suitable for entry into a body vessel. The examiner acknowledge this fact on page 5 of the Examiner's Action by stating, "Boyd et al. ... disclose using a deployable pad to cool tissue, but do not specifically disclose a method of use within a blood vessel."

Nor does the Boyd et al. reference, either alone or in a proper combination with other references, render either claim 1 or 10 obvious. In particular, the presently claimed medical device is a new structure that provides functionality that not only cannot be achieved by Boyd et al. or any other reference, but is also not even contemplated by Boyd et al. or any other reference. In particular, the presently claimed device has an elongate body with a distal end suitable for entry into a body vessel that may be directed through the body vessel and positioned near a target tissue region in the body. Once positioned, a deployable structure, which in the case of claim 10 is a patch, may be deployed from the elongate body to cool the target tissue region. The claimed device permits the targeted cooling, by direct contact, of tissue located either inside the heart or inside another organ. The prior art does not disclose a device that makes this type of cooling possible. For example, the cooling in Boyd et al. is performed by cooling the tissue on the outside of the heart.

In addition, prior art catheters, such as is shown in the Ginsberg reference, do not provide the necessary teaching to render either of claims 1 or 10 obvious. In particular, there is no suggestion in any prior art to combine the teachings of Boyd et al. with prior art catheters, nor would it be feasible to combine these references. For example, the catheter in Ginsburg is not even for cooling tissue by direct contact, as is contemplated by Applicant's claimed devices. In Ginsburg, by contrast, the catheter cools the blood as it flows through a blood vessel, and specifically states that the balloon should not be inflated to contact tissue in the blood vessel. In other words, Ginsburg teaches away from the use of the deployable heat exchanger that contacts tissue inside the body as disclosed in Boyd et al.

Moreover, the heat exchanger of the hypothermia device disclosed in Boyd et al. is intended for topical cooling of the entire tissue region on the underside of the heart (i.e., the outside surface of the heart), and is too large to be deployed inside the body. The claimed device is suitable for cooling tissue that is, for example, inside a heart chamber. Boyd et al. does not suggest this application, and thus does not suggest the claimed structure that may be used in this application.

In addition, the hypothermia device of Boyd et al. has a tubular shaft made of a rigid material, such as stainless steel (col. 21, lines 12-14). The rigid shaft is delivered through an access cannula that has an internal diameter of about 10-12 millimeters (col. 21, lines 43-45). The access cannula provides a short, straight path for insertion of the hypothermia into the chest of the patient. Not only do body vessels have a much smaller inner diameter than the access cannula disclosed in Boyd et al., but they are also much longer and do not provide a straight path that can accommodate a device with a rigid shaft. Consequently, one of skill would not look to Boyd et al. for cooling via body vessels. Also, because of the size restraints presented by the inner diameter of a body vessel, there is no motivation to combine the teachings of Boyd et al. and Ginsburg, which disclose a patch and a balloon that each occupy the entire distal end of their respective devices. Further, the patch in Boyd et al. has a retractable sleeve that moves back and forth over the same area of the device that would contain the balloon disclosed in Ginsburg, which would prevent the balloon from functioning.

Accordingly, both claim 1 and claim 10, as amended, define an invention that is patentable over Boyd et al. and all other prior art of record. Claims 2-4, 7-9, 11-18 and 23-24 each depend either directly or indirectly from claim 1 or claim 10. Therefore, these dependent claims are also patentable over Boyd et al. and all other prior art of record. Accordingly, the Applicant asks that the Examiner remove his rejections of these claims.

Method Claim 35 and its Dependents

The combined teachings of Boyd et al. and Ginsberg do not render the method of independent claim 35 obvious. As discussed previously, the heat exchanger in Boyd et al. is intended for direct contact to body tissue, whereas Ginsburg specifically states that the balloon should not be inflated to contact tissue. In addition, the claimed method is intended for cooling tissue that is, for example, inside the heart chamber. In contrast, the device is Boyd et al. is intended for topical cooling on the outside of the heart.

Moreover, contrary to the Examiner's contention that the patch in Boyd et al. is designed for delivery via a small diameter cannula, the patch is actually delivered through an access port in the chest of the patient that has an internal diameter of 10-12 millimeters and provides a short,

straight path for the insertion of the device. Because body vessels have a much smaller inner diameter than the access cannula disclosed in Boyd et al. and body vessels do not provide a short, straight path that can accommodate a device with a rigid shaft, one of skill would not look to Boyd et al. for cooling via body vessels. Further, as explained previously, the combination of Boyd et al. and Ginsburg, which discloses a catheter that cools via blood vessels, would not be feasible due to the size and operation of the respective devices.

Accordingly, independent claim 35 defines an invention that is patentable, as does claim 36, which depends from claim 35. The Applicant asks that the Examiner withdraw his rejection of these claims.

Added Claims 40-43

Added independent claim 40 is a rewriting of claim 38 in independent form, which the Examiner indicated would be allowable if so written. Dependent claims 41-43 are similar to claims 36, 37, and 39, respectively, and each depend from independent claim 40. Accordingly, Applicant submits that claims 40-43 are in condition for allowance and ask the they be allowed.

Consideration of Non-Elected Dependent Claims

Pursuant to 37 CFR 1.142(b), the examiner withdrew claims 5-6, 19-22, 25-34 and 37 from consideration as being drawn to a non-elected invention. Claims 5-6 depend from claim 1, claims 19-22 depend either directly or indirectly from claim 10, and claim 37 depends from claim 35.

As discussed previously, claims 1 and 10 have been amended to recite an elongate body having a distal end for entry into a body vessel and are now in condition for allowance. Similarly, claim 35, as originally filed, covers a method that involves introducing a catheter having an elongate body into a body vessel, and is also in condition for allowance. Because the pending generic claims 1, 10, and 35 are allowable, and the claims that depend from these generic claims are written in dependent form and include all of the limitation of the generic claims, Applicant contends that dependent claims 5-6, 19-22, and 37 are entitled to consideration and allowance pursuant to 37 CFR 1.141, and asks that the Examiner consider them.

CONCLUSION

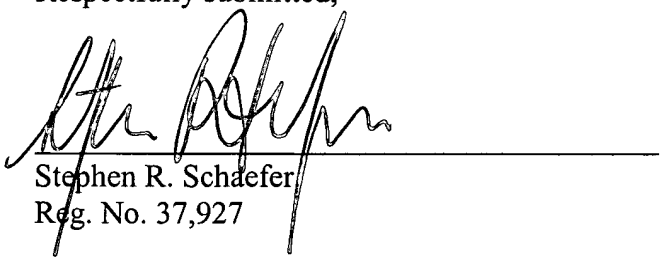
Applicant submits that all pending claims 1-24 and 35-43 are in condition for allowance and respectfully requests that the examiner issue a notice of allowance. Upon reviewing the file, Applicant notes that an initialed copy of the PTO Form 1449 that accompanied the Supplemental Information Disclosure Statement filed January 11, 2005, was not received with the Examiner's action. Thus, Applicant also requests that the initialed Form 1449 be returned to Applicant in the next communication, indicating that the references have been considered.

It is believed that all of the pending claims have been addressed. However, the absence of a reply to a specific rejection, issue or comment does not signify agreement with or concession of that rejection, issue or comment. In addition, because the arguments made above may not be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to its amendment.

No fee is believed due. Please apply any other charges or credits to deposit account 06-1050.

Respectfully submitted,

Date: April 18, 2005



Stephen R. Schaefer
Reg. No. 37,927

Fish & Richardson P.C., P.A.
60 South Sixth Street
Suite 3300
Minneapolis, MN 55402
Telephone: (612) 335-5070
Facsimile: (612) 288-9696